Decision Memo for Multiple-Seizure Electroconvulsive Therapy (CAG -00134N)

Decision Summary

We have examined the medical and scientific evidence as well as the additional information obtained as a result of our own investigation. We have determined that the available evidence is adequate to conclude that MECT may pose additional safety risks over conventional ECT for patients with affective disorders or other psychiatric disorders without a balancing clinical benefit.

We have also found that the available evidence, limited to case reports, is not adequate to conclude that non-routine use of MECT is warranted for medical conditions such as neuroleptic malignant syndrome and intractable seizures that do not respond to other therapies.

Therefore, MECT (including the practice of routinely initiating treatment with double-seizure ECT) is considered not reasonable and necessary for the treatment of psychiatric and non-psychiatric conditions in the Medicare population. We intend to issue a national non-coverage decision for use of MECT for all indications.

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Decision Memo

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SUBJECT: Coverage Decision Memorandum for Multiple Electroconvulsive Therapy (MECT)
DATE: November 19, 2002

This memorandum serves four purposes: (1) provides background on the clinical use of electroconvulsive therapy (ECT), in general, and multiple ECT (MECT), in particular; (2) reviews past Medicare coverage of MECT and provides a timeline of recent CMS activities related to the coverage of MECT; (3) presents and analyzes the relevant scientific and clinical literature related to MECT; (4) delineates supporting reasons and outlines the agency's intention to issue a noncoverage determination for this procedure under the statutory authority of section 1862 (a)(1)(A) of the Social Security Act.

Clinical Background

Electroconvulsive therapy is a treatment for severe mental illness in which a brief electrical stimulus is applied to the scalp to produce a seizure lasting approximately one minute. The seizure induction is carried out under general anesthesia, assisted ventilation with positive pressure oxygen, and after administration of a muscle relaxant drug. The muscular relaxant used in the procedure prevents the body from convulsing while the short-acting general anesthesia prevents the patient from feeling pain or having consciousness of the muscular paralysis or electrical charge.

Although ECT has been in use for over 60 years, there has been ongoing controversy concerning the specific mental disorders for which ECT is indicated, its efficacy in their treatment, the optimal methods of administration, possible complications, and the extent of utilization in various settings.[1] ECT was first introduced as a treatment for schizophrenia but was quickly found to be more effective in patients with affective disorders, including both depressive and manic states. The effectiveness of ECT for treatment of severe depression has been well established. It has been used for a wide variety of other conditions as well, although with less scientific support.[2] ECT is most commonly given to patients who have not responded to other treatments or when alternative treatments pose a greater risk of adverse effects.

Use of ECT in the United States has recently increased with an estimated 100,000 patients receiving the procedure each year. Middle and upper socioeconomic groups are disproportionately represented among ECT recipients. Studies also show a steady increase in ECT utilization with age.[3] Rates of ECT use by geographic area are highly variable, higher than for most medical and surgical procedures. Only a small proportion of the variation in ECT use is likely to be attributable to variation in the prevalence of depression, the condition most commonly treated with ECT. The extent of variation suggests psychiatrists continue to lack consensus regarding the use of the procedure.[4]

The extent to which ECT is a primary treatment or is considered only after patients have not responded to other interventions also varies. ECT is utilized as a primary treatment in severe major depression with psychotic features, mania with psychotic features, and catatonia due to its rapid response and efficacy in these conditions relative to other therapies. However, as mentioned above, the procedure is most often used in patients with severe affective disorders, who have not responded to other treatments. For major depression, this would, at a minimum, include one or more adequate antidepressant medication trials.[5]

Appropriate application of ECT, including assisted ventilation, brief anesthesia, muscular relaxation, and physiologic monitoring is associated with a very low rate of morbidity and mortality. The majority of deaths associated with ECT are due to cardiorespiratory causes.[6] With the advent of current techniques, many of the medical complications have been eliminated.[7] Complications and adverse effects of ECT can be divided into the following two categories:

(1) Medical complications, such as prolonged seizures (more than two minutes) and cardiac arrhythmias, that can be substantially reduced by the use of trained staff and appropriate methods of administration

(2) Side effects, such as memory loss and transient post-treatment confusion, that can be expected even when optimal treatment methods are utilized. For instance, deficits in memory function for events before and after ECT (retrograde and anterograde amnesia, respectively) may persist following termination of a course of treatment and have been the root of much controversy regarding use of ECT in general. [8]

Method of administration

The course of therapy varies but typically ranges from six to twelve treatments, administered as a single treatment two or three times weekly, on alternate days.[9] Technical factors in ECT administration (e.g., form of stimulus, electrode placement, and stimulus dosage) can strongly influence efficacy and adverse effects. For instance, unilateral ECT is associated with a shorter confusional state and fewer memory deficits than the bilateral electrode placement method. Also, a brief pulse stimulus is associated with fewer cognitive adverse effects and is more efficient in eliciting seizures than the traditional sine wave-shaped stimulus. Seizure threshold varies greatly among patients and may need to be determined at the initiation of treatment for each individual patient. Electrical dosing in excess of seizure threshold may result in more severe cognitive effects than does near threshold treatment.[10]

Calls have been made "to better identify subgroups for which the treatment is particularly beneficial or toxic and to refine techniques to maximize efficacy and minimize side effects."[11] Considerable evidence regarding the roles of stimulus intensity, seizure threshold, and seizure durations has been produced in recent years.[12] Although it has been established, for instance, that right unilateral ECT causes less severe cognitive adverse effects than bilateral ECT, the relative efficacy of these electrode placement techniques has been the subject of controversy.[13] The extent to which practitioners use unilateral or bilateral electrode placement varies considerably. Some practitioners use unilateral or bilateral ECT exclusively. Others start patients with unilateral ECT and switch to bilateral ECT if patients fail to respond adequately. Some practitioners increment the dosage of right unilateral ECT before switching to bilateral ECT. A further alternative is to initiate bilateral ECT in patients whose psychiatric or medical status requires a greater assurance of rapid clinical response.[14] Thus, the question of what constitutes the optimal technique for administering ECT to various patient subgroups has not been completely answered.

Use in the elderly

There is evidence of more frequent ECT use in the elderly than in non-elderly patients. In 1986, the national estimate was that 15.6% of inpatients 65 years of age or older with mood disorders received ECT. The rate was 3.4% among younger inpatients with mood disorders.[15] Medication resistance, medication intolerance (at times related to the interactions with the many medicines used by the elderly to treat coexisting disorders), the need for more rapid clinical improvement than with pharmacotherapy, and a higher rate of psychotic depression in late life have been cited as reasons for the broadened role of ECT in treating this population.[16]

Older patients with depression may have comparable outcomes with ECT as younger patients but present with greater rate of complications during and after ECT treatment. Common complications in the elderly include severe confusion following termination of the seizure (usually referred to as post-ictal confusion), falls, and cardiorespiratory problems. At particular risk are patients over 75 years of age, in poor health, and those taking multiple medications, particularly cardiovascular agents.[17] [18] Seizure threshold may rise with increasing age and effective seizures may be more difficult to induce.[19]

Multiple Electroconvulsive Therapy (MECT)

MECT is a form of treatment in which two to eight adequate seizures are induced in the same treatment session under continuous anesthesia. This procedure was originally called multiple-monitored electroconvulsive therapy (MMECT) because its proponents developed the practice of monitoring both the electrocardiogram (ECG) and electroencephalogram (EEG) in the course of a treatment session when multiple seizures were induced.[20] However, all impulse-generating units currently utilized for delivering conventional single-seizure ECT provide ECG and EEG monitoring capabilities. Since both single and multiple ECT are monitored procedures, we simply refer to them in the text as single (SECT) or multiple ECT (MECT). Treatment sessions of multiple ECT should be distinguished from those where more than one charge is delivered to determine the patient's seizure threshold and from those where one or more failed attempts to induce an adequate seizure precede a successful induction. These are considered instances of single ECT. Finally, multiple ECT should not be confused with maintenance ECT, which is also frequently abbreviated in the literature as MECT.

Proponents of MECT have suggested that a smaller number of treatment sessions might produce the same results as with conventional ECT with no increased incidence of adverse reactions.[21] [22] Some practitioners reportedly reserve use of this technique for patients who have a high anesthetic risk or an urgent need for rapid onset of therapeutic response. Others limit the number of seizures in a treatment session to two.[23] It has been suggested that producing two or more adequate seizures in the same session in the treatment of patients with neuroleptic malignant syndrome or intractable seizure disorder may be justified, although conventional ECT has also been reported to alleviate these medical conditions. [24] [25] Critics of the method argue that MECT has not been shown to be more effective than conventional ECT and that it is associated with a higher risk of neurologic and cardiovascular morbidity as well as adverse cognitive effects such as post-ictal confusion and memory impairment.[26]

FDA Status

The Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act established three regulatory classes for medical devices. ECT devices were already in commercial distribution at that time. Subsequently, in September 1979, the FDA published a final rule classifying ECT devices into class III. Devices in this class usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury.

A manufacturer is required to submit to FDA a premarket approval (PMA) application for a new class III device, unless the device has been in commercial distribution before 1976 or is substantially equivalent to a device already on the market. Specifically, under 510 (k) of the Food, Drug and Cosmetic Act, manufacturers can market a medical device in the United States, if they demonstrate to the agency's satisfaction that it is substantially equivalent (as safe and effective) to a device already on the market. New ECT devices, therefore, may currently be cleared under section 510 (k) provisions.

In response to a petition submitted by the American Psychiatric Association (APA) in 1982 to reclassify ECT, the FDA proposed on September 5, 1990 to reclassify the ECT device from class III (device requiring premarket approval) into Class II (requiring a performance standard) when intended only for use in treating severe depression. The proposed rule made the reclassification for that indication contingent upon the establishment of a performance standard. The FDA believed that "the risks associated with ECT are primarily related to the technique of administration and to the duration and nature of the patient's exposure to the device. (…) A performance standard is necessary to assure the safe and effective use of the ECT device." [27]

The Safe Medical Devices Act of 1990 (the SMDA) subsequently changed the definition of class II devices from those for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to those for which there is sufficient information to establish special controls to provide such assurance. These controls include, for example, clinical data in premarket notification (PMN) submissions in accordance with section 510 (k).

The SMDA also directed the FDA to revise the classification of certain class III devices, including ECT, and either reclassify them into class I or class II or retain them in class III. The FDA has required that manufacturers of ECT devices submit to the agency a summary of all information available, including adverse safety or effectiveness information, concerning those devices. Pending final FDA action on this matter, ECT devices remain classified in class III.

Medicare's Coverage for MECT

There is no national policy on the use of SECT or MECT. These procedures are considered physician services as defined under section 1861(s)(1), "Medical and Other Health Services," of the Social Security Act. At least 12 Medicare contractors have developed local medical review policies for this service based on Section 1862 (a)(1)(A) of the Social Security Act. Subsequent to the recent release of the OIG report mentioned below regarding the use of MECT, one contractor located in Puerto Rico has revised its local medical review policy to exclude MECT from coverage.

Timeline of Recent Activities

The Office of the Inspector General (OIG) at the Department of Health and Human Services regularly conducts program evaluations that focus on issues of concern to the Department, the Congress and the public. In December 2001, the OIG issued a report on the use of MECT in the Medicare population (represented by the current procedural terminology or CPT code 90871). The report indicated, "Recent objective reviews have suggested that MECT should not be part of a routine clinical treatment." However, claims data obtained by the OIG revealed that the rate of use of MECT under the Medicare program exceeded what would be expected for a procedure that should only be used rarely. Although the OIG did not make a formal request for a change in Medicare national coverage policy, it recommended that CMS consider the appropriate use of CPT code 90871. CMS concurred with this recommendation and determined that the findings in the report were significant enough to warrant a review of the scientific evidence on this procedure.

The agency proceeded to develop a national coverage determination (NCD) to assess whether the literature supported the findings of the OIG report and to determine to what extent, if any, MECT should be covered under Medicare. On April 22, 2002, CMS posted a tracking sheet on the agency's website (00134N), formally initiating the NCD process on this subject. The agency has received no comments from professional organizations or the general public since posting the decision to review the use of MECT.

Summary of Evidence

Systematic review

General methodological principles of study design

When making national coverage determinations, CMS staff review relevant trials to determine whether or not the data is of sufficient quality to support a finding of clinical effectiveness. CMS considers several generally accepted methodological principles when assessing clinical studies.[28] We evaluate, for instance, whether general methods of study design have been followed, such as specifying inclusion and exclusion criteria describing and the process for the selection of study participants, and the ways in which the consistency of this selection process was maintained. Other concerns include ensuring comparability of experimental and control groups at baseline, describing baseline characteristics of the participants, randomizing study subjects, masking of patients and investigators to the therapy administered, describing co-interventions in detail, and performing appropriate statistical analyses (e.g., statistical tests of differences in baseline characteristics between the comparison groups). CMS evaluates other study design issues, which, in the case of MECT, include the following:

- Has an appropriate outcome been used?
- Was the appropriate patient population studied?
- Have appropriate measures of endpoints been selected, identified prior to initiating the trial, and standardized across all study sites? Have clear measurement criteria been provided?
- Have the process used to measure the selected outcomes and methods with which the study investigators ensured the consistency of this process across different study sites been described?
- Have all subjects, regardless of the protocol arm to which they are assigned (investigational treatment or control), received the same standard of care? Has the standard care been described in detail?
- Have variables that may affect results been addressed in the analysis (e.g., stimulus duration, shape and charge, electrode placement, and time elapsed between stimuli)?
- Have adequate follow-up evaluations been performed?

Assessment questions

CMS staff developed assessment questions prior to performing a systematic review of the available evidence on the effects of MECT. Analysts also requested information from experts and professional societies and reviewed evidence-based practice guidelines and position papers on this topic. The safety and effectiveness of MECT was only critically appraised in comparison, whenever possible, with conventional ECT. The clinical effectiveness of conventional ECT compared to other treatments for mental illness (e.g., drug therapy) was not the focus of this review. Two questions were posed to structure the systematic review of the literature.

- Does MECT improve outcomes in patients with major depression or other psychiatric disorders compared to conventional ECT?
- Does MECT improve outcomes in patients with non-psychiatric conditions compared to conventional ECT?

All patients that received MECT as a therapeutic intervention were included in the review. Outcomes considered were beneficial or adverse clinical effects of MECT, such as remission of depressive symptoms, rate of recovery, decreased anesthesia time, post-ictal confusion, memory loss, and neurologic and cardiac complications.

Literature search strategy

The following were the defined inclusion/exclusion criteria for the literature search:

- Studies had to be comparative and could have any methodological design.
- Studies could include persons of any sex, ethnic origin and age that received MECT.
- Case series and case reports would not be excluded when patients served as their own controls.
- Studies could be conducted in any setting and reported in English.

Studies were identified by performing an electronic search of the Medline database from its creation to May 2002 using the text words "ECT", "electroconvulsive therapy", "electro-convulsive therapy", "MECT", "MMECT," and "multiple". Records were limited to humans.[29] We then reviewed the abstracts of the relevant references and selected articles for retrieval. We identified additional articles through manual search of references of relevant articles. We screened the full-text of retrieved articles to determine whether they met the inclusion criteria for the review and extracted data from eligible studies.

Search results

Ten articles were included in the review. Key data from these studies appear in the evidence tables in the Appendix. We grouped the articles in two sets, depending on whether the treated condition was psychiatric or involved other medical disorders.

Seven studies, including one randomized controlled trial, focused on the use of MECT for persons with mental illness, primarily major depressive illness (evidence table 1). The following is a summary of the main design features for these studies.

- Two prospective comparisons that used contemporaneous control groups. One of the prospective studies was randomized (Roemer 1990); the other was observational (Maletzky 1986).
- Two retrospective comparisons that used a non-contemporaneous control group (Berens, Yesavage, 1982; Yesavage, Berens, 1980). The majority of the data in the two studies referred, however, to the same patient population.
- A retrospective comparison of two treatment groups (elderly vs. non-elderly) that lacked a control group (Mielke 1984).
- One case series (Abrams 1972) and a case report (Strain 1971) that included patients who had received SECT serving as their own historical controls.

The remaining three studies (Griesemer 1997; McKinney 1997; Zeindenberg 1976), all case reports, documented use of MECT for patients with neurological disorders (evidence table 2).

Critical appraisal of the evidence

The most recent study on the effects of MECT for patients with serious depressive illness, published by Roemer and colleagues in 1990, overcame some of the major sources of bias affecting the other six studies, all predating Roemer. Among the methodological flaws encountered in the other studies were lack of consistency in methods of ECT application (e.g., multiple practitioners delivering ECT), use of historical controls, unspecified diagnosis, non-standardized rating scales, and non-randomized assignment of patients.

The study by Roemer et al. (1990) compared double-seizure ECT with the conventional ECT schedule of one seizure induction per treatment day. This was the only prospective randomized clinical trial available in the literature on MECT. However, the study design was not free of sources of systematic error. For example, even though patients and research associates rating patients' depressive symptoms were blind to the treatment received, attending psychiatrists and those in the team delivering ECT were not. These practitioners determined completion of the course of ECT and documentation of side effects, thus opening the possibility of intervention and observation biases.

Furthermore, researchers did not focus directly on side effects of potential interest (e.g., acute and sub-acute memory impairment) and relied solely on chart entries for measurement of such side effects, acknowledging that chart notes are less sensitive than testing and may be influenced by the clinicians' awareness of treatment. In spite of this methodological weakness, preventing an accurate assessment of net health outcome, the study showed that 10 of the 16 patients receiving double-seizure ECT had chart entries documenting clinically significant confusion (disorientation to time and place, difficulty in finding rooms, and difficulty in recognizing staff on the unit). In contrast, only 2 of 13 patients treated with single inductions manifested confusion.

With respect to clinical effectiveness, the study measured clinical outcomes after session 4 and post-treatment (i.e., after the last treatment or the eighth ECT session). The authors found a more rapid amelioration of depressive symptoms with MECT (patients receiving this procedure had lower depression ratings after the fourth session than those in the SECT group), but no statistically significant difference in rating scale depression scores at the end of treatment between the two groups. The total number of seizures at the end of treatment did not differ significantly between groups.

A number of inherent design weaknesses in the prospective study by Maletzky (1986) calls into question the validity of its conclusions concerning the risks and benefits of MECT. The author did not describe the inclusion criteria for study subjects nor the baseline demographic and clinical parameters (age, sex, diagnosis) of the experimental and control populations, providing little assurance that these groups were similar at baseline. Lack of randomization and assignment of intervention by attending physicians made selection bias likely. With regard to method of application, ECT was not consistently applied in either group since different practitioners performed the procedures. Clinicians delivering the procedure were aware of the patients' clinical status, thus creating conditions for intervention bias. Finally, although effectiveness was measured at 5 days, 6 months and 12 months post-treatment, side effects were not described beyond 5 days after treatment. Although the study results showed no differences in effectiveness and side effects between the groups receiving MECT and SECT, the report noted that prolonged seizures were a more frequent intra-session complication in the MECT group.

The study by Mielke et al. (1984) is a comparison of two treatment groups by age (elderly vs. non-elderly). The retrospective nature of the study and, in particular, the absence of matched control groups prevents drawing any direct scientific conclusions regarding the relative safety and clinical effectiveness of MECT compared to conventional ECT. In spite of these and other methodological shortcomings such as the absence of reporting or analysis regarding side-effect data by age group, the study is informative for its high incidence of serious complications and side effects among patients receiving MECT. These include, for instance, a myocardial infarct in a 72 year-old patient with normal ECG at admission and a post-ictal confusional state (that lasted seven days) in a patient receiving lithium. These outcomes are rarely seen with appropriate application of conventional ECT and raise questions about the safety of MECT in general, and in the elderly in particular.

Berens and Yesavage (1982) reported on a retrospective comparison between subjects receiving MECT and historical controls receiving SECT. The authors took advantage of a change in the routine ECT method of application from SECT to MECT that took place in 1977 at a Veterans Administration hospital to compare the effect of both methods. For patients with depression, the study found no statistically significant differences in clinical benefit or side effects but reported a significant reduction in the number of days of treatment, ECT sessions, and dosage of muscle relaxant for patients undergoing MECT. The methodological flaws inherent in a retrospective review (e.g., any changes other than the type of ECT applied – in milieu, drug regimens or staffing that may have taken place in the different periods observed), call into question the comparability of the therapeutic interventions. Also limiting the validity of the findings were the small number of patients, the uncertain baseline comparability of groups, and the fact that several patients received both ECT and MECT.

The same authors had previously reported on MECT for a population of 25 patients with depression (Yesavage and Berens, 1980). The study group included 20 patients over 45 years of age (labeled "elderly") evenly divided to have received SECT and MECT. The population and study design in the 1982 and 1980 studies were very similar with the exception that the newer study added five patients to the SECT group and dropped the criterion of age greater than 45 years as a requirement for inclusion in the analysis. These changes resulted in a larger total number of observations for both comparison groups but did not modify study findings (i.e., similar safety and effectiveness for both interventions, shorter duration of treatment, fewer sessions, lower dosage of anesthetic agents for MECT). The methodological weaknesses discussed in reference to the 1982 study are also applicable to the retrospective comparison originally published in 1980 and similarly undermine the validity of its findings.

The rest of the articles reviewed included case reports and case series. Case series are generally considered a weak and potentially misleading form of evidence concerning the effect of therapeutic interventions. The main flaw of case studies is the lack of direct comparison with another group receiving an alternative treatment. However, case reports may be useful in bringing attention to larger than expected or more frequent occurrence of adverse events when compared with the outcomes of the standard treatment. In the series published by Abrams, et al (1972), for example, the authors noted more prolonged confusional states in patients receiving more seizures per session.

The incidence or size of adverse events can be compared more readily when individual patients serve as their own controls. The case report by Strain (1971) documented a very prolonged seizure (more than 50 minutes) and a cerebrovascular accident after the fourth seizure during the first treatment session in a 62 year-old patient who had had two previous depressive episodes successfully treated with SECT without untoward effects.

Case reports can also document the use of a procedure in special circumstances and suggest new indications for further study. The three remaining articles included in this review, all case reports, illustrate individual cases where MECT was used, alone or in combination with SECT, for certain conditions when other therapeutic interventions were not available or had been ineffective. Conditions included intractable seizures in a 13 year-old boy (Griesemer, 1997), neuroleptic malignant syndrome in a 19 year-old woman (McKinney, 1997), and depression in a 31 year-old man with muscular dystrophy (Zeidenberg, 1976).

Position Statements

The American Psychiatric Association (APA) recently published an evidence-based task force report with recommendations for practitioners regarding use of ECT. An APA task force reviewed the available clinical literature by searching all citations related to ECT published between 1989 and 1998 that had been entered into the MEDLINE database by December 1998. The literature review was supplemented by suggestions from experts and association members. To provide a comprehensive set of recommendations, the task force included material based on empirical findings as well as clinical consensus for those situations in which well-controlled clinical trials were either unavailable or not applicable. The recommendation of the task force with regards to MECT, which constitutes official clinical policy for the APA, is reproduced below.

"Given the concerns about the safety of eliciting multiple adequate seizures in the same treatment session and the absence of evidence about putative advantages, routine use of MECT is not recommended. Occasionally, with urgent clinical circumstances, producing two adequate seizures in the same session may be justified. It has been suggested that this practice is useful in the treatment of patients with neuroleptic malignant syndrome and intractable seizure disorder. Eliciting three or more adequate seizures in the same treatment session is not recommended." [30]

Expert Opinion

The National Institutes of Health (NIH) Consensus Statements are prepared by a non-advocate, non-federal panel of experts based on presentations by investigators, open questions and statements from conference attendees, and closed panel deliberations. The last Consensus Development Conference Statement issued by NIH on ECT states

"Multiple-monitored ECT (several seizures during a single treatment session) has not been demonstrated to be sufficiently effective to be recommended." [31]

In a recently issued professional guide for the layperson, Dr. Max Fink, a psychiatrist who has published extensively on ECT use, refers to coverage of MECT under Medicare as follows.

"Doctors at one time hoped that several seizures in a single day, under one period of anesthesia – multiple monitored ECT (MMECT) – would ensure clinical success without repeated use of anesthetics. But some patients still suffered memory loss, disorientation, and confusion lasting many days, without experiencing any advantages, so such schedules are not encouraged today." On a related note, the author adds: "An invidious twist in Medicare reimbursement rates allows extra payments to physicians who administer more than one seizure in a treatment. This economic incentive encourages the use of MMECT despite its acknowledged risks and lack of increased efficacy." [32]

Various clinical experts we informally consulted in the course of this review indicated that use of MECT has been largely discouraged among clinicians in recent years, citing concerns about the higher incidence of side effects.

CMS Analysis

National coverage determinations (NCDs) are determinations made by the Secretary regarding whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act, § 1869(f)(1)(B). In order to be covered by the Medicare program, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not otherwise be excluded from coverage. Moreover, section 1862 (a)(1)(A) of the Act requires, with limited exceptions, that the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

This section examines the evidence available on the safety and clinical effectiveness of MECT to determine whether this intervention is reasonable and necessary and therefore meets the statutory requirement for coverage under the Medicare program. Clinically effective for this therapeutic intervention means that the procedure causes an equal or greater improvement in net health outcomes than any established alternatives used to treat the same indication in the same population in the same clinical setting. As noted in the assessment questions, the discussion addresses two sets of indicationspsychiatric conditions for which conventional ECT is primarily indicated, such as major depressive disorders, and medical conditions not responsive to other therapies.

Benefits from MECT claimed for patients with psychiatric disorders, primarily with depressive and bipolar disorders, include

- More rapid amelioration of depressive symptoms, in particular for patients at high risk of suicide, progressive inanition, or excitement with risk of exhaustion or assault
- Shorter course of treatment; shorter time a patient is severely depressed
- Reduced number of anesthetic inductions
- Reduced side effects and complications

Our critical appraisal of the evidence, utilizing well-accepted principles of study design, shows that the literature supporting use of this procedure reflects substantial methodological shortcomings. These include poor description of process for selection of study participants, little assurance that experimental and control groups were comparable or that the same standard of care was provided to both groups, lack of contemporaneous controls, outcome measurements based on clinical impressions of treating psychiatrists, and inadequate follow up evaluations.

In spite of the likelihood of bias favoring the intervention and contrary to the claims of the original advocates of MECT, none of the comparative studies reviewed showed that MECT produced fewer side effects than conventional ECT at the end of treatment. The best-designed study available, a prospective randomized double-blind comparison between single-seizure and double-seizure ECT by Roemer (1990), showed accelerated recovery from depressive symptoms, but failed to show that the remission rates at the end of treatment varied for both groups.

The benefit of accelerated rate of recovery described in studies reporting use of MECT is overshadowed by the findings of increased safety risks. The two prospective studies reviewed, even though designed in a manner likely to underreport side effects and complications, reveal a higher incidence of untoward effects for MECT patients. In addition, other studies reviewed including the retrospective comparison of elderly and non-elderly MECT patients by Mielke (1984) and the case reports by Abrams (1972) and Strain (1971) indicate that MECT is associated with increased risk of neurological and cardiovascular complications as well as more serious cognitive side effects than conventional ECT. For instance, the very prolonged seizures (e.g., longer than five minutes) described in patients receiving MECT are rarely observed during conventional ECT treatment.

The major events in the anesthetized and paralyzed patient with current conventional methods of application are cardiovascular responses such as blood pressure elevation, tachycardia and other cardiac dysrhythmias. How these events are modified by MECT when seizures are repeated at short intervals has not been well documented. The report by Strain (1971) describing a cardiovascular accident in a patient receiving MECT who had previously responded therapeutically to SECT with no untoward effects and the occurrence reported by Mielke (1984) of a myocardial infarct in a patient with normal ECG at admission raise concerns about the higher incidence of complications with MECT and question the safety of the technique.

The increased risk resulting from use of MECT described in the articles reviewed is of particular concern to Medicare beneficiaries in light of the already higher morbidity associated with conventional ECT in the elderly population. In particular, those over age 75 may be at several-fold higher risk than younger patients for severe confusion, falls, and cardiorespiratory complications.

In addition, the purported clinical advantage of an accelerated recovery may be of less significance today than when MECT was first proposed since exposure to anesthesia is no longer a major risk of ECT. Furthermore, excess confusion or complications associated with MECT may conceivably interrupt the course of routine ECT treatment, delaying recovery and increasing the length of hospitalization.

Finally, the psychiatric conditions for which MECT has been advocated (i.e., agitation, intense suicidality, self starvation) are included among the indications for conventional ECT. Depending on the severity of the psychiatric condition, clinicians already have discretion to modify the various methods of application of single-seizure ECT (e.g., by increasing the number of sessions at the beginning of treatment, switching from unilateral to bilateral application, altering the dose of electrical stimulus) before increasing the number of seizures induced in one session.

The available clinical literature illustrating the non-routine use of MECT for neurological conditions such as NMS and seizure disorders is limited to a couple of case reports. This evidence is not sufficient to conclude that MECT is an effective alternative intervention for these conditions. However, there may be specific clinical circumstances in which MECT and, particularly, double-seizure ECT would be useful. If so, CMS would consider any new evidence for narrowly defined non-routine uses of MECT should requests for coverage of specific patient subgroups be submitted in the future.

Decision

We have examined the medical and scientific evidence as well as the additional information obtained as a result of our own investigation. We have determined that the available evidence is adequate to conclude that MECT may pose additional safety risks over conventional ECT for patients with affective disorders or other psychiatric disorders without a balancing clinical benefit.

We have also found that the available evidence, limited to case reports, is not adequate to conclude that non-routine use of MECT is warranted for medical conditions such as neuroleptic malignant syndrome and intractable seizures that do not respond to other therapies.

Therefore, MECT (including the practice of routinely initiating treatment with double-seizure ECT) is considered not reasonable and necessary for the treatment of psychiatric and non-psychiatric conditions in the Medicare population. We intend to issue a national non-coverage decision for use of MECT for all indications.

1 National Institutes of Health. Electroconvulsive therapy, Consensus development conference statement. June 1985. (NIH. *ECT Consensus Statement.*)

2 Task Force Report of the American Psychiatric Association. *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training, and Privileging*. Second edition. 2001. (APA. *The Practice of Electroconvulsive Therapy.*)

3 R Herman et al. Variation in ECT use in the United States. American Journal of Psychiatry. June 1995. The nationwide rate estimate in this study was approximately 5 patients per 10,000 population of persons older than 15 years of age. No ECT use was reported in 115 metropolitan statistical areas (36%). Among the remaining 202 metropolitan statistical areas studied, ECT use varied from less than 0.5 per 10,000 population in the lowest-use area to more than 80 per 10,000 population in the highest-use area.

4 *Ibid.*

5 APA*. The Practice of Electroconvulsive Therapy.*

6 C Welch, L Drop. Cardiovascular effects of ECT. *Convulsive Therapy.* 5: 35-43. 1989.

7 NIH. *ECT Consensus Statement.*

8 *Ibid.*

9 *Ibid.*

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27 55 Fed Reg. 36, 578, 36, 581 (September 5, 1990). The criteria defining a standard suggested by FDA included labeling contents (e.g., priority order of treatment, such as progression from unilateral to bilateral electrode replacement; treatment protocols; clinical indications and contraindications, etc.) and design features (e.g. control energy output, duration, and frequency of stimulus charge.)

28 Numerous useful texts have been published on general trial design and evidence-based medicine describing these principles in more detail. For example, M Egger et al*. Systematic Reviews in Health Care: Meta-Analysis in Context*. BMJ Publishing Group, 2001; C Mulrow, D Cook . *Systematic Reviews: Synthesis of Best Evidence for Health Care Decisions*. American College of Physicians, 1998.

29 We updated the search on October 1, 2002 and found that no additional relevant material had been published with the exception of a letter to the editor reporting on the use of MECT in an individual case.

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